UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,720	01/17/2006	Haruo Imawaka	Q92718	1473

65565 7590 07/18/2008
SUGHRUE-265550
2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
ZUCKER, PAUL A	
ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
07/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUL 18 2008

SUGHRUE-265550
2100 PENNSYLVANIA AVE. NW
WASHINGTON DC 20037-3213

In re Application of:
Imawaka et al.
Serial No.: 10/564,720
Filed: January 17, 2006
Attorney Docket No.: Q92718

: PETITION DECISION

This is in response to the petition under 37 CFR § 1.181, filed June 13, 2008, requesting that the finality of the Office action of April 15, 2008 be withdrawn.

BACKGROUND

In brief, the examiner mailed a non-final Office action on September 13, 2007 setting a three month statutory limit for reply. At the time of this non-final Office action, claims 1-19 were pending in the application and examined on their merits. *Inter alia*, the examiner rejected claims 11-18 under 35 U.S.C. 112, first paragraph. In said rejection, the examiner stated:

> ...[The]specification, while being enabling for treatment of some neurodegenerative disorders, does not reasonably provide enablement for prevention of any disorder or treatment of disorders such as brain cancer or Down's Syndrome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.... the breadth of the claims: In the instant case the claims are extremely broad encompassing compositions and methods for the prevention of any form of neurodegenerative condition including brain cancer in all its various forms, Down's disease or syndrome, Creutzefeld-Jacob disease, Huntington's disease, etc... (pp. 2-3, non-final Office action of September 13, 2007)

In reply to the non-final Office action of September 13, 2007, applicants filed remarks and arguments, along with an amendment on December 13, 2007.

On April 15, 2008, claims 1-10 and 19 were pending and examined. Among other rejections, the examiner rejected claim 19 under 35 U.S.C. 112, first paragraph. Specifically, the examiner indicated:

> NOTE: Claim 19 was omitted from this rejection by clerical error. Applicants should have recognized that since the limitations of claim 19 were addressed, it should have properly been included. The following rejection is therefore made FINAL. Claim 19 is finally rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of some neurodegenerative disorders, does not reasonably provide enablement for prevention of any disorder or treatment of disorders such as brain cancer or Down's Syndrome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims

In response thereto, applicants filed this petition on June 13, 2008, requesting that the finality of the Office action of April 15, 2008 be withdrawn.

DISCUSSION

The petition and the file history have been carefully considered.

In the petition filed on June 13, 2008 applicants argue that the rejection set forth by the examiner in the final Office action of April 15, 2008 was premature and improper because, as applicants allege, the examiner instituted a new ground of rejection in the final Office action upon rejecting claim 19 under 35 U.S.C. 112, first paragraph. In support of their contentions, applicants correctly indicate that the first Office action on the merits did not explicitly include claim 19 in the 35 U.S.C. 112, first paragraph, scope of enablement rejection along with claims 11-18.

> Applicants correctly indicate:
>
> The MPEP states that under current U.S. PTO practice, second or any subsequent actions on the merits shall be final, except where the Examiner introduces a new ground of rejection that is neither necessitated by Applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 C.F.R. §1.97(c) with the fee set forth in 37 C.F.R. §1.17(p). See MPEP § 706.07(a) (p. 2, Petition)
>
> Additionally, applicants state:
>
> Although the Examiner states that claim 19 was omitted from the previous enablement rejection in the Action dated September 13, 2007 due to clerical error, it remains that claim 19 was not rejected in the previous Action and the present rejection of claim 19 is a new ground of rejection that was not necessitated by Applicants' amendment. Additionally, canceled claims 11-16 were directed to an agent and canceled claims 17-18 were directed to a medicament, while claim 19 is directed to a method for preventing and/or treating a neurodegenerative disease. Thus, it was not unreasonable to consider that the Examiner would treat the different types of claims in a different manner. (p. 2, Petition).

Applicants thus assert that the examiner's rejection of claim 19 under 35 U.S.C. 112, first paragraph, in the final Office action was a new ground of rejection which was not necessitated by applicants' amendment to the claimed invention and thus argue that the Office action of April 15, 2008 was improperly made final and that said finality should be rightfully removed.

However, it is seen that claims 1-19, originally examined, were directed toward compounds and pharmaceutical compositions lacking any intended use (claims 1-10), a pharmaceutical composition useful as a preventative and/or therapeutic agent for a neurodegenerative disease (claims 11-16), a medicament (claims 17 and 18) and a method for preventing and/or treating a neurodegenerative disease (claim 19).

Thus, there was only one method claim pending at the time the first Office action was rendered; specifically claim 19. To reiterate from above, the examiner clearly indicated in the rejection made under 35 U.S.C. 112, first paragraph: "In the instant case the claims are extremely broad encompassing compositions and **methods for the prevention of any form of neurodegenerative condition** including brain cancer in all its various forms, Down's disease or syndrome, Creutzefeld-Jacob disease, Huntington's disease, etc..." (emphasis added).

The examiner provided further analysis of the scope of the claimed invention as compared with conventional knowledge regarding prevention of neurodegenerative disorders:

> ....c. the state of the prior art: the state of the prior art is such that many of the disease states recited such as brain cancer in all its various forms, Down's disease or syndrome, Creutzefeld-Jacob disease, Huntington's disease, etc. have no known treatment and no known method of prevention by pharmaceutical means. For example, there is no pharmaceutical method for the prevention of Down's syndrome, which is a genetic disorder (p. 4, non-final Office action of September 13, 2007.

Therefore, it is clear that the examiner rejected claims involving methods for prevention of any neurodegenerative condition even though the rejection did not expressly include the rejection of claim 19 upon commencement of said rejection. Analysis of the content of the rejection indicates that the examiner explicitly stated that the method claims were not enabled for their scope and provided reasons for such a finding. It is thus decided that the omission of claim 19 from the original rejection made under 35 U.S.C. 112, first paragraph, was indeed an error of clerical nature. Applicants were provided keen information in the examiner's rejection which as a whole indicates that claim 19 was, in fact, rejected under 35 U.S.C. 112, first paragraph.

Therefore, contrary to applicants' assertions, the rejection of claim 19 under 35 U.S.C. 112, first paragraph, in the final Office action rendered on April 13, 2008 is not considered to be a new ground of rejection. Applicants' arguments are not found persuasive and the final Office action mailed April 13, 2008 will not be withdrawn.

DECISION

The petition is **DENIED.**

Should there be any questions about this decision please contact Marianne C. Seidel, by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0584 or by facsimile sent to the general Office facsimile number, 703-872-9306.

Irem Yucel
Director, Technology Center 1600

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Haruo IMAWAKA, et al.

Appln. No.: 10/564,720

Confirmation No.: 1473

Filed: January 17, 2006

Docket No: Q92718

Group Art Unit: 1621

Examiner: Paul A. Zucker

For: BRANCHED CARBOXYLIC ACID COMPOUND AND USE THEREOF

PETITION TO WITHDRAW FINALITY UNDER 37 C.F.R. § 1.181

ATTN: Technology Director
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit that the final Office Action dated April 15, 2008, improperly has been made final and thus respectfully solicits withdrawal of the finality of the Office Action.

Specifically, the Examiner sets forth at least one new ground of rejection which was not necessitated by Applicants' amendments nor based on information submitted in an information disclosure statement filed during the period set forth in 37 C.F.R. §1.97(c) with the fee set forth in 37 C.F.R. §1.17(p). See MPEP § 706.07(a).

Namely, the Examiner has newly rejected claim 19 for lack of enablement under 35 U.S.C. §112, 1st paragraph, and has made the Action final. This new §112, 1st paragraph rejection is a new ground of rejection, which is neither necessitated by amendment nor is it based on information submitted in an information disclosure statement filed during the period set forth

in 37 C.F.R. § 1.97(c) with the fee required in 37 C.F.R. § 1.17(p). This contravenes current practice. The MPEP states that under current U.S. PTO practice, second or any subsequent actions on the merits shall be final, **except** where the Examiner introduces a new ground of rejection that is neither necessitated by Applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 C.F.R. §1.97(c) with the fee set forth in 37 C.F.R. §1.17(p). See MPEP § 706.07(a).

The Examiner recognizes that the §112, 1st paragraph rejection is a new ground of rejection, and states that claim 19 was omitted from the previous enablement rejection in the Action dated September 13, 2007 due to clerical error. The Examiner further asserts that Applicants should have recognized that claim 19 should have been included in the §112, first paragraph, enablement rejection because the same limitations were addressed in the rejection of claims 11-18.

Applicants disagree with the Examiner's position on raising a new ground of rejection and making the Action final. Although the Examiner states that claim 19 was omitted from the previous enablement rejection in the Action dated September 13, 2007 due to clerical error, it remains that claim 19 was not rejected in the previous Action and the present rejection of claim 19 is a new ground of rejection that was not necessitated by Applicants' amendment. Additionally, canceled claims 11-16 were directed to an agent and canceled claims 17-18 were directed to a medicament, while claim 19 is directed to a method for preventing and/or treating a neurodegenerative disease. Thus, it was not unreasonable to consider that the Examiner would treat the different types of claims in a different manner.

In view of the above, since Applicants are limited in the action that can be taken after a final rejection as a matter of right, Applicants submit that making the rejection final is improper as a procedural matter for the reasons set forth above. Namely, that the Examiner has raised a new ground of rejection that is neither: (1) necessitated by Applicants' Amendment, nor (2) based on information submitted in an information disclosure statement requiring a fee under 37 C.F.R. § 1.17(p).

For the reasons discussed above, Applicants request that the finality of the Office Action be withdrawn.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

Susan J. Mack / Bruce E. Kramer Reg. No. 33,725

Susan J. Mack
Registration No. 30,951

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860
WASHINGTON DC SUGHRUE/265550
65565
CUSTOMER NUMBER

Date: June 13, 2008